

Docket No.: 1408.017  
U.S. Serial No.: 09/882,382  
Applicant: LEH *et al.*

### REMARKS

Claims 1-10, which were present in the application as originally filed, were amended and new claims 11-17 presented by a preliminary amendment filed with the application. Claims 1-17 are, therefore, presently pending in the application. Reconsideration of the application in view of the amendments above and remarks following is respectfully requested.

#### Rejections under 35 U.S.C. §102

Claims 1 and 3 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,035,894, to Lee, *et al.* The rejection is traversed.

The Lee patent relates to adhesive compositions including blends of polyethylene oxide-grafted silicone polymers with resinous copolymers, and transdermal drug delivery devices incorporating these adhesive compositions (Abstract). Claim 1 is now amended to limit the composition of the adhesive layer of the transdermal preparation to a solution-type acrylic having a poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether side chain. These polymers are derived from alkyl (meth)acrylate monomers with (meth)acrylate monomers having a pendant poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether side chain, or by attaching the side chain to the backbone after polymerization of the alkyl (meth)acrylate monomers alone (specification, page 6, line 23 - page 7, line 6). As the Lee patent discloses only adhesives having a siloxane backbone, and makes no mention of *acrylic* adhesives, Applicants submit that claim 1 and claim 3, which depends from claim 1 and contains the limitations thereof, are not anticipated by the reference. It is believed that the rejection is hereby overcome.

Claims 1, 2, 16 and 17 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,779,632 to Dietz, *et al.* The rejection is traversed

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Dietz relates to a adhesive composition prepared by photopolymerization of an aqueous microemulsion (Abstract) that may include polyethylene oxide acrylate monomers/oligomers (col. 10, lines 31-43). As noted above, with the amendments to Claim 1 presented herewith, the composition of the claimed transdermal preparation is now limited to solution-type acrylic polymers for the adhesive layer. These polymers are prepared by a solution polymerization process (specification, Example 1, (D)-(I)) in order to avoid the disadvantage of using emulsion-type acrylic adhesives in a composition containing a drug that is hydrophilic or in the form of a salt, as discussed on page 3, lines 13-17, of the specification. Formulating a drug in salt form into an emulsion polymer in an amount sufficient to have the desired therapeutic effect can cause breaking of the emulsion, and subsequent agglomeration of the polymer. As a consequence, loading of the drug in the adhesive composition may be limited. Applicants submit that Dietz does not teach a solution-type polymer as a component of an adhesive layer, and so does not anticipate claim 1, or dependent claims 2, 16 and 17. It is believed that the rejection is overcome.

### Rejections under 35 U.S.C. §103

Claims 2, and 4-15 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,035,894 to Lee, *et al.*, in view of U.S. Patent No. 5,865,792 to Ledger, *et al.* Claims 3, 6-11, and 13-15 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,779,632 to Dietz, *et al.*, in view of U.S. Patent No. 5,865,792 to Ledger, *et al.* The rejections are traversed.

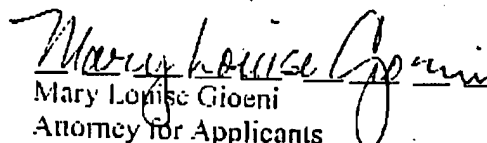
The teachings of the Lee and Dietz patents are set forth above. Ledger relates to an electrotransport device for delivering an ionized drug wherein the drug is contained in a reservoir (claim 1). The matrix of the reservoir may be composed of a hydrophilic polymer, including blends of polyethylene oxide with polyacrylic acid (col. 9, lines 15-35). The device may contain an adhesive applied to the face of the reservoir; composition of the adhesive is unspecified (col. 5, lines 60-67).

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Neither Lee nor Dietz disclose a transdermal preparation composed of a solution-type acrylic adhesive, as set forth above, and there is no suggestion in either patent that such an adhesive composition be used for transdermal delivery of a drug. Ledger fails to supply this deficiency, as the patent is completely silent regarding the composition of an adhesive. Therefore, Applicants submit that claims 2-4, 6-11 and 13-15 are not obvious over either Lee or Dietz, in view of Ledger. It is believed that the rejection is hereby overcome.

*Respectfully submitted,*

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Mary Louise Gioeni  
Attorney for Applicants  
Registration Number 41,779

Heslin Rothenberg Farley & Mesiti, P.C.  
5 Columbia Circle  
Albany, New York 12203  
Telephone: (518) 452-5600  
Facsimile: (518) 452-5579

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